



BILLING CODE: 4165-15

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Discretionary Advisory Committee on Heritable Disorders in Newborns and Children;

Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463, codified at 5 U.S.C. App.), notice is hereby given of the following meeting:

**NAME:** Discretionary Advisory Committee on Heritable Disorders in  
Newborns and Children

**DATES AND TIMES:** February 12, 2015, 8:30 a.m. to 5:00 p.m.  
February 13, 2015, 9:00 a.m. to 4:00 p.m.

**PLACE:** Webinar and In-Person  
National Institutes of Health  
5635 Fishers Lane  
Rockville, Maryland 20857

**STATUS:** The meeting will be open to the public with attendance limited to space availability.

Participants also have the option of viewing the meeting via webinar. Whether attending in-person or via webinar, all participants must register for the meeting. The registration link will be made available at <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders/>.

The registration deadline is Friday, January 30, 2015, 11:59 p.m. Eastern Time.

**PURPOSE:** The Discretionary Advisory Committee on Heritable Disorders in Newborns and Children (Committee), as authorized by Public Health Service Act (PHS), 42 U.S.C. 217a: Advisory councils or committees, was established to advise the Secretary of the Department of Health and Human Services about the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. In addition, the Committee's recommendations regarding additional conditions/inherited disorders for screening that have been adopted by the Secretary are included in the Recommended Uniform Screening Panel (RUSP) and constitute part of the comprehensive guidelines supported by the Health Resources and Services Administration. Pursuant to section 2713 of the Public Health Service Act, codified at 42 U.S.C. 300gg-13, non-grandfathered health plans are required to cover screenings included in the HRSA-supported comprehensive guidelines without charging a co-payment, co-insurance, or deductible for plan years (i.e., policy years) beginning on or after the date that is 1 year from the Secretary's adoption of the condition for screening.

**AGENDA:** The meeting will include: (1) a final report on the Mucopolysaccharidosis 1 (MPS 1) Condition Nomination for inclusion on the Recommended Uniform Screening Panel (RUSP), (2) a final report on the Laboratory Procedures and Standards Subcommittee's Timely Newborn Screening Project, (3) a presentation from the U.S. Preventive Services Task Force on the transfer of newborn screening topics (sickle cell disease, phenylketonuria, congenital hypothyroidism) to the Committee, (4) update on the condition review of Adrenoleukodystrophy (ALD), (5) update from the Pilot Study Workgroup and discussion on the different mechanisms and challenges for implementing pilot studies, (6) presentation on analyzing costs when implementing screening for a new condition, (7) presentation by the Newborn Screening

Translational Research Network Long-term Follow-up Project, and (8) updates on priority projects from the Committee's subcommittees on Laboratory Standards and Procedures, Follow-up and Treatment, and Education and Training.

The Committee is expected to vote on whether or not to recommend to the Secretary the addition of MPS 1 to the RUSP. Tentatively, the Committee is expected to review and/or vote on the final recommendations on timely newborn screening. Agenda items are subject to change as necessary or appropriate. The agenda, webinar information, Committee Roster, Charter, presentations, and other meeting materials will be located on the Advisory Committee's website at <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders>.

**PUBLIC COMMENTS:** Members of the public may present oral comments and/or submit written comments. Comments are part of the official Committee record. The public comment period is tentatively scheduled for both days of the meeting. Advance registration is required to present oral comments and/or submit written comments. Registration information will be on the Committee website at

<http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders>. The registration deadline is Friday, January 30, 2015, 11:59 PM Eastern Time. Written comments must be received by the deadline in order to be included in the February meeting briefing book. Written comments should identify the individual's name, address, email, telephone number, professional or business affiliation, type of expertise (i.e., parent, researcher, clinician, public health, etc.), and the topic/subject matter of comments. To ensure that all individuals who have registered to make oral comments can be accommodated, the allocated time may be limited. Individuals who are associated with groups or have similar interests may be requested to combine their comments and present them through a single representative. No audiovisual presentations are permitted.

For additional information or questions on public comments, please contact Lisa Vasquez, Maternal and Child Health Bureau, Health Resources and Services Administration; email: [lvasquez@hrsa.gov](mailto:lvasquez@hrsa.gov).

**CONTACT PERSON:** Anyone interested in obtaining other relevant information should contact Debi Sarkar, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18A-19, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857; email: [dsarkar@hrsa.gov](mailto:dsarkar@hrsa.gov).

More information on the Advisory Committee is available at <http://www.hrsa.gov/advisorycommittees/mchbadvisory/heritabledisorders>.

Jackie Painter,  
Acting Director, Division of Policy and Information Coordination.

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